NTP Proposed Revisions to Report on Carcinogens Review Process: Public Listening Session Comment

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Objectives of RoC

- Government [work products] must be
 - "...transparent
 - ...participatory
 - ...collaborative
 - ...[to] promote efficiency and effectiveness" (President Obama, March, 2009)
- The proposed RoC process revisions, absent more detail, are not consistent with these objectives in several major areas of concern

Weight of Evidence

Proposed process revision:

- Continues "strength of evidence" approach, i.e., presenting only case for listing
- Absent any criteria for robust "weight of evidence" integrated analysis (NAS, 2011)
 - Human exposure context; dose-response assessment
 - Mode of Action frameworks: strengths and weakness of proposed MOA; alternative considerations
 - standardized criteria for selection & review of scientific information a "must"
 - Transparency on all information/data considered

Valuing Public Input

- Lacks adequate positioning and clarity in "time(s)" of process
 - External comment not solicited until NTP Concept paper is drafted
 - No definition of reasonable time to receive public comments on draft Concept or RoC Monograph
 - No clarity on time needed for external reviewers to evaluate external comments, or time needed to present critical concerns to review panels
 - NTP response to public comment not expected
 - For 12th RoC, NTP responses delivered only after final listing

Effective Peer Review

- Process lacks criteria for type of peer review
- Peer review fails to exploit value of public inputs
 - Adequate time for peer reviewer evaluation
 - Lacks NTP responses to public comments to guide peer reviewer evaluations
- Charge of Peer Reviewers too limited
- Selection process of peer reviewers not identified
- Lacks review by other federal agencies
- Denies HHS leadership important insights into controversies of data consideration and interpretation

Summary

NTP RoC proposed revisions:

- further hinder transparency, participatory and collaborative efforts in development of RoC work products
- constrain science-informed decision making on key public health documents